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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,847	04/27/2006	Giovanni Cipoletti	207,567	6763

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EXAMINER

KOSAR, AARON J

ART UNIT	PAPER NUMBER
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1651

MAIL DATE	DELIVERY MODE
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11/12/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/577,847	Applicant(s) CIPOLETTI ET AL.	
	Examiner AARON J. KOSAR	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-7 and 10-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-7 and 10-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Amendment

Applicant's amendment and argument filed June 19, 2008 in response to the non-final rejection, are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed is herein withdrawn.

Applicant has amended the claims by canceling claims 4, 8, and 9. Claims **1-3, 5-7, and 10-20** are pending and have been examined on the merits.

Claim Objections

Claims 19 and 20 are objected to because of the following informalities:

In claim 19, the word "Method" in the claim preamble appears to be a typographical error of the word "A method".

In claim 20, the phrase "a) strong base..." appears to be a typographical error of the phrase "a) a strong base" (emphasis added).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Response to Arguments

Applicant has argued that solutions and suspensions are synonymous. Applicant has also argued that the method steps provide for a complete method. Applicant's arguments have been fully considered, but respectfully, for the reasons of record and those provided herein, they are not persuasive.

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With respect to Applicant's arguments that a solution and suspension are equivocal terms; to the contrary, suspensions and solutions describe compositions with different phase behavior/interrelationships (e.g. a solid-liquid suspension versus a dissolved solute in solution) and thus solutions are not suspensions (and vice versa); however, it is noted that the specification provides literal and/or implicit support for suspensions and/or solutions to the extent instantly claimed, and thus renders such arguments moot.

Claims 1-3, 5-7, 10-18, and 20 are/remain rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01.

Claims 1-3, 5-7, 10-18, and 20 are incomplete for omitting essential steps. While all of the technical details of a method need not be recited, the claims should include enough information to clearly and accurately describe the invention and how it is to be practiced. The minimum requirements for method steps minimally include a *providing/contacting step* in which the necessary reagents and the reaction of the sample with said reagents is recited; a *detecting/reacting step* in which the reaction steps are quantified, visualized, or effected; and a *concluding/correlating step* describing how the steps/results of the reaction allow for/provide the product.

The claims are drawn to "a process for the preparation of galactose" (method of making galactose), however, the claims positively recite the active steps of: "*maintaining*"; "*stopping* the base addition"; "*obtaining* a suspension"; "*recovering* a solution", and "*removing* the biomass", are the only positively recited active steps in the claims. The claims are incomplete because they lack a providing/contacting step(s) (e.g. inoculating a milk or milk serum...) and a concluding/correlating step(s). [Please note the progressive ("-ing") form of the positively recited

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active steps versus the passive or prophetic constructs (e.g. is inoculated, is fermented, is left/allowed).] Thus, one would not be apprised as to the subject matter Applicant intends to embrace by the claims, rendering the method incomplete and the claims therefrom indefinite.

Claims 1-3, 5-7, and 10-20 are/remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 16, and 17 recite the limitation “*the* biomass”. There is insufficient antecedent basis for this limitation, because claim 1 does not recite “*a* biomass”.

Claims 1-3, 5-7, and 10-20 are indefinite, because claims 1 and 18 are unclear. Claims 1 and 18 are unclear, because the preamble to claim 1 recites a method of preparing galactose from “milk or milk serum not subjected to any preliminary removal of the protein portion of milk”; however, claim 1 recites the starting material species of “milk serum” and claim 18 further recites that prior to step (i) the milk/milk serum may be subjected to pasteurization, each of which recitation may broadly and reasonably be interpreted as a preliminary and purification treatment or a pretreated, purified compounds therefrom. Additionally, as taught by FOOD RESOURCE (U1: PTO-892: Food Resource, “Whey, Milk Serum, Serum Lactis” <<http://food.oregonstate.edu/glossary/w/whey.html>> archived online 9/4/2006 (accessed 11/5/2008), 1 page.), milk serum, also known as whey or lactoserum, “is the portion of skim milk after the coagulation and separation of casein” and thus is inconsistent with a composition having not been subjected to removal of the protein portion, thereby rendering indefinite the phrase “milk serum...not subjected to removal of the protein portion of milk”. Because the claim body and method steps are unclear and internally inconsistent with the preamble, one would not

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be apprised as to the subject matter Applicant intends to embrace by the claims, rendering the claims indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Response to Arguments

Applicant has argued that Torino does not teach industrial scale or how galactose is recovered. Applicant's arguments have been fully considered but they are not persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., industrial scaling and precluding HPLC recovery) are not recited in the rejected claim(s). Furthermore, the beneficial teachings of Torino with respect to "removal of the cells by centrifugation" (page 847 right column, ¶1), centrifugation, purified EPS, and analysis to provide quantified mM concentrations/amounts of galactose, each anticipate recovery of galactose or biomass-reduced compositions as the compositions as taught by Torino would intrinsically be biomass-reduced/biomass-free/biomass-separated compositions comprising galactose to the degree or purity and to the extent claimed. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

With respect to Applicant's arguments that *L. helveticus* is not representative of other organisms, for example the elected species combination of *S. thermophilus* with *L. bulgaricus*, to

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the extent that Torino and the instantly elected species combination differ, Torino demonstrates the non-allowability of the generic invention and thus is maintained as anticipating the claims under 35 USC 102(b) to said extent. Applicant's arguments are thus found to be not persuasive; and the ground of rejection is thus maintained.

Claims 1-3, 5, 6, 10-15, and 18-20 are/remain rejected under 35 U.S.C. 102(b) as being anticipated by TORINO (U:PTO-892).

The claims are generally drawn to a method comprising: inoculating milk/serum; obtaining galactose; maintaining a constant pH over a period of time, by adding inorganic base; and recovery of a galactose solution.

TORINO anticipates the generic invention, teaching a species of *Lactobacillus* microorganism contacted with skim milk at a controlled pH, including pH 6.2 maintained with aqueous ammonia (ammonium hydroxide); fermented for times including 16 hours, including additional 0,8,12,16,20, 24, etc. hour increments; and HPLC/chromatographic recovery of the galactose component of the product mixture (see for example, materials and methods). Torino also teaches the effect of pH on the production rates and concentrations of acids, consumption of lactose (i.e. production of glucose and galactose) sampled during exponential growth (12 hours)(table 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Response to Arguments

Applicant has argued that the microorganisms of the instant invention provide for the unexpected use of gal-negative *S. thermophilus* and mixtures containing said bacteria (and not containing yeast) to surprisingly provide gal-positive activity and high levels of galactose. Applicant has also argued that the references do not provide for galactose crystallization.

Respectfully, this is not found to be persuasive, because these features upon which Applicant relies are not recited in the rejected claim(s). Additionally, the instant claims are not commensurate with the showing of the unexpected argued/alleged by Applicant, and said features of the unexpected are also not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Claims 1-3, 5-7, and 10-20 are/remain rejected under 35 U.S.C. 103(a) as being unpatentable over ACUNA (V:PTO-892) and MOORE (A:PTO-892: US 2,974,044) and TURNER (W:PTO-892).

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The claims are generally drawn to a method comprising: inoculating (milk) serum; obtaining galactose; maintaining a constant pH over a period of time, by adding inorganic base; and recovery of a galactose solution.

ACUNA teaches that microorganism cultures, including *S. thermophilus* and/or a *Lactobacillus* species (e.g. *L. bulgaricus*) fermented with a milk serum composition comprising: mild whey (milk serum) and 40g/L lactose (4.0%(w/v)). Acuna teaches that the fermentation produces galactose and lactic acid as the microorganisms consume lactose (figure 1). Acuna also teaches that lactate/lactic acid are inhibitory to growth and that optimal fermentation conditions for the organisms tested were:

- (a) *S. thermophilus* (i.e. *S. salivarius* subsp. *thermophilus* 404): pH 6.5, 40°C;
- (b) *L. bulgaricus* (i.e. *L. delbrueckii* subsp. *bulgaricus* 398): pH 5.8, 44°C; and
- (c) Mixed culture ((a)+(b)): pH 6.5, 42°C,

wherein the culture solutions were pH-controlled by adding NaOH and temperature-controlled for 5-7 hours. Acuna also teaches recovering galactose by HPLC on a cation exchange column. (see *Materials and Methods*). Acuna still further teaches that galactose-positive strains (gal⁺) and galactose-negative strains (gal⁻) produce galactose in low and high levels of accumulation, respectively (abstract).

MOORE teaches that pH of a fermentation media, including media wherein acids may accumulate, may be adjusted by addition of “NaOH, KOH, Ca(OH)₂, NH₄OH, sodium carbonate, etc... within a range of 2.1 to 8.5” (column 4).

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TURNER teaches that *Lactobacilli* species which are capable of cleaving lactose into lactic acid are differentiated by their abilities to metabolize glucose and/or galactose. Turner also teaches that glucose (MRS) broth supported growth for all species of *Lactobacillus* tested, that galactose (MRS) broth containing <0.01% glucose was selective for select species of *Lactobacillus*, and that galactose broth containing even 0.02% glucose impurity in a galactose-enriched media is sufficient to elicit false-positive results for galactose utilization which may explain the intermixed properties among species, including for example *L. bulgaricus* and *L. helveticus* (various, e.g. table 1). This constitutes a teaching that galactose utilization/fermentation (gal^+ versus gal^-) may be used as a major characteristic in assessing an organism's industrial (e.g. dairy fermentation) suitability (page 1933, ¶1).

Turner also teaches that *S. thermophilus* produces galactose from lactose, that *S. thermophilus* is commonly used in combination with gal^- strains of lactobacilli, including in the production of yoghurt (page 1933, ¶3). Turner still further teaches that *S. thermophilus* and gal^- *Lactobacilli* are incapable of fermenting free galactose or the galactose moiety of lactose (page 1932, last ¶ and portion spanning page 1933).

Acuna differs from the instantly claimed invention in that Acuna is silent with respect to the consumption of glucose and fermenting for 16 to 24 hours.

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It would have been obvious to use a microorganism to consume the glucose produced by lactose breakdown into galactose and glucose, because Acuna teaches species of microorganism, including, *S. thermophilus*, *L. bulgaricus*, and the combination thereof, which produce galactose from lactose-containing substrate. Additionally, Turner teaches that microbes of the claimed genus, *S. thermophilus*, are known to hydrolyze lactose to galactose, are known to be combined with gal⁻ strains of *Lactobacilli*, and that gal⁻ *Lactobacilli* (*L. lactis* and *L. lactis*-like or lactic acid-insensitive *L. bulgaricus*) are known (page 1932, ¶3; page 1933, ¶3 and table 1).

One would have been motivated to use a gal⁻ microbe because Turner teaches fermenting of gal⁻ microbes in lactose-containing culture (skim milk) to produce a residual galactose concentration.

One would have had a reasonable expectation of success in using a gal⁻ microbe, because Acuna teaches that galactose production is affected by lactic acid/lactate and acidity, because lactose breakdown into galactose would intrinsically produce glucose which, according to Turner, supports growth of microbes of the claimed species.

It would have been obvious to ferment for 16 to 24 hours because Acuna teaches fermenting of cultures over time, including the increase of galactose in mixed culture from 0-400 minutes partially hydrolyzes the lactose present, and because Turner teaches that fermenting for 24 hours at 37°C.

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One would have been motivated to optimize the time of reaction because Acuna teaches that the reaction is incomplete at the maximum time (upward sloped-trend, figure 1) and because Turner teaches reacting by fermenting for 24 hours. Additionally, it would have been obvious to one skilled in the art at the time of invention to determine all optimum and operable conditions (e.g. reaction time, temperature of an enzymatic reaction, substrate concentrations), because such conditions are art-recognized result-effective variables that are routinely determined and optimized in the art through routine experimentation. ("[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). See MPEP § 2145.05).

Acuna, Turner, and Moore are relied upon for the reasons discussed above. If not expressly taught by these references, based upon the overall beneficial teaching provided with respect to recovery of galactose in the manner disclosed therein, the selection of a known purification method and the adjustments of particular conventional working conditions (e.g., determining one or more suitable ranges in which to perform such a purification/isolation), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan, especially in the absence of evidence to the criticality of a particular feature in effecting galactose production and recovery as claimed or in the absence of evidence to the contrary.

The MPEP states, "A prima facie case of obviousness may be made when chemical compounds have very close structural similarities and similar utilities. "An obviousness rejection based on similarity in chemical structure and function entails the motivation of one skilled in the

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art to make a claimed compound, in the expectation that compounds similar in structure will have similar properties.” *In re Payne*, 606 F.2d 303, 313, 203 USPQ 245, 254 (CCPA 1979). See *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) and *In re Dillon*, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1991).” See MPEP § 2144.09. In the instant case it would have been obvious to substitute NaOH for another base, because MOORE teaches that NaOH, KOH, Ca(OH)_2 , $\text{NH}_4\text{(OH)}$, etc. are known inorganic bases, having known metal-hydroxide/metal-carbonate chemical structures, and functioning for the same utility, to effect pH control of fermentation media.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

35 USC § 112, 2nd ¶ (Miscellaneous Note)

Please note, the following claims language in sample claims 1,19, 21, and 22 are provided for Applicant’s convenience and which in addition to appropriately amending the

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dependent claims, would be sufficient to traverse the grounds of rejection *to the extent rejected under 35 U.S.C. 112, 2nd ¶*, for example:

1. A method of preparing galactose from milk or milk serum, the method comprising:

i) providing

a) milk, wherein said milk is not subjected to any preliminary removal of a protein portion of said milk; or

b) milk serum,

wherein said milk or said milk serum does not contain any bactericides or bacteriostats;

ii) inoculating said milk or said milk serum with wild-type microorganisms, thereby providing a suspension, wherein said microorganisms are able to hydrolyze lactose in said milk or said milk serum into galactose and glucose and able to consume said glucose;

iii) fermenting the suspension of step (ii), said fermenting comprising maintaining said suspension at a constant pH value between 5 and 7.5 for a period of time between 16 and 24 hours, by adding a base of inorganic origin to said suspension;

iv) acidifying the fermented suspension of step (iii) for a period of time ranging between 5 and 60 hours, said acidifying comprising stopping the adding of said base to said fermented suspension, thereby decreasing the pH of the suspension and obtaining a suspension enriched in galactose; and

v) removing a biomass from the suspension enriched in galactose of step (iv), thereby recovering a solution of galactose,

wherein said biomass comprises said microorganisms and said microorganisms comprise *Streptococcus thermophilus*, and wherein said base of inorganic origin is selected from the group consisting of sodium hydroxide, potassium hydroxide, calcium hydroxide, magnesium hydroxide, calcium carbonate, and ammonia.

19. A method of disposing of milk serum derived from dairy industry, the method comprising:

i) providing milk serum containing lactose of at least 2.5% by weight of said milk serum, wherein said milk serum does not contain bactericides or bacteriostats;

ii) inoculating said milk serum with wild-type microorganisms able to hydrolyze lactose into galactose and glucose and able to consume said glucose, wherein said microorganisms comprise *Streptococcus thermophilus*; followed by,

iii) fermenting said inoculated serum of step (ii), said fermenting comprising maintaining said inoculated serum at a constant pH value ≤ 7.5 for a period of time between 16 and 24 hours, by adding a base of inorganic origin, wherein said base is selected from the group consisting of sodium hydroxide, potassium hydroxide, calcium hydroxide, magnesium hydroxide, calcium carbonate, and ammonia, thereby providing a fermented product; and, finally,

iv) recovering a galactose solution from the fermented product.

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21. The method of any one of claims 1 or 19 wherein said microorganisms further comprise *Lactobacillus bulgaricus*.

22. The method of claim 21, wherein said microorganisms further comprise *Lactobacillus casei*.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. KOSAR whose telephone number is (571)270-3054. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday,EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Aaron J Kosar/
Examiner, Art Unit 1651

/Sandra Saucier/
Primary Examiner, Art Unit 1651